ROLE OF INDUCED SPUTUM IN THE DIAGNOSTIC WORKUP OF PULMONARY TUBERCULOSIS IN CHILDREN

Dissertation submitted to

THE TAMIL NADU DR.M.G.R.MEDICAL UNIVERSITY

In partial fulfillment of the regulations

for the award of degree of

M.D DEGREE (PEDIATRICS) BRANCH VII

INSTITUTE OF CHILD HEALTH AND
HOSPITAL FOR CHILDREN
MADRAS MEDICAL COLLEGE

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CERTIFICATE

This is to certify that the dissertation titled, **"Role of Induced sputum in the Diagnostic workup of Pulmonary Tuberculosis in Children"** submitted by **Dr.C.Vijai Shankar,** to the Faculty of Pediatrics, The Tamil Nadu Dr.M.G.R Medical University, Chennai, in partial fulfillment of the requirements for the award of M.D. Degree (Pediatrics) is a bonafide research work carried out by him under our direct supervision and guidance, during the academic year 2009-2012.

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DECLARATION

I, **Dr.C.Vijai Shankar**, solemnly declare that the dissertation titled **"Role of Induced sputum in the Diagnostic workup of Pulmonary Tuberculosis in Children"** has been prepared by me.

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Institute of Child Health and
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dated:

The Institutional Review Board [Ethical committee] of Institute of Child Health and Hospital for Children, Chennai-08, was held on 30.01.2010 at 10.00AM at the Deputy Superintendents chamber.

Members Present: Dr.R.Kulandai Kasthuri
Chair Person.

Members:
1. Dr.K.Gita
2. Dr.P.Jeyachandran
3. Dr.D.Vijaya Sekaran
4. Prof.Girija Shyam Sundar
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6. Dr.P.Ramachandran
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Member Secretary: Dr.Luke Ravi Chellaiah

Title: "Role of Induced Sputum in the Diagnostic Work up of Pulmonary Tuberculosis in Children".

The Institutional Review Board was satisfied with the revised format submitted by you. Hence the Institutional Review Board is pleased to approve the study.

To,
Dr.C.Vijai Shankar,
Post Graduate,
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Director and Superintendent.

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CONTENTS

INTRODUCTION

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Tuberculosis is an infectious disease caused by Mycobacterium tuberculosis, which most commonly affects the lungs. It is transmitted from person to person via droplets from the throat and lungs of people with the active respiratory tuberculosis disease. Left untreated, each person with active tuberculosis disease will infect on average between 10 and 15 people every year and this continues the tuberculosis transmission. Overall, one-third of the world's population is currently infected with the tuberculosis bacillus. 5-10% of the people who are infected with tuberculosis bacilli become sick or infectious at some time during their life. **(1)**

India is the country with highest tuberculosis burden accounting for one fifth (21%) of the global incidence. India is 17th among 22 high burden countries in terms of tuberculosis incidence rate. It is estimated that about 40% of Indian population is infected with tuberculosis bacillus. The prevalence of tuberculosis has been estimated at 3.8 million bacillary cases for the year 2000, by an expert group of Govt. of India. **(1)**

Children can present with tuberculosis at any age and the majority of cases present between 1 and 4 years. Pulmonary tuberculosis in children is usually paucibacillary (smear negative).

Bacteriological confirmation of pulmonary tuberculosis in infants and children is difficult due to the following reasons:

1. Due to minimal disease or infiltration,
2. Without extensive cavitations,
3. Difficulty in coughing out the sputum. **(2)**

Gastric lavage (GL) is regarded as the standard procedure to obtain specimens for staining and culture of Mycobacterium tuberculosis in younger children because they swallow their sputum and do not expectorate. Since gastric lavage cause inconvenience to the child, and the yield low smear positivity on microscopy, this procedure should only be used where culture is available as well as microscopy. **(3)**

Sputum induction with hypertonic saline helps in obtaining adequate amount of sputum and increasing positivity rate. It is safe, simple, cost effective and less time consuming procedures. It is a non invasive method which is well tolerated with minor side effects of increased cough, epistaxis and vomiting. Sputum induction provides sample for both culture and AFB staining. It can be done postprandially as outpatient department procedure. **(4)**

Sputum for acid fast bacilli usually were smear positive in less than 15% and mycobacterial culture yields are 30% to 40%. In the absence of

bacteriological confirmation, the diagnosis of childhood tuberculosis in countries where tuberculosis is not endemic is based on a triad of close contact with an infectious patient, a positive tuberculin skin test, and presence of suggestive abnormalities on a chest radiograph. These criteria, however, have limited application in countries where tuberculosis is endemic. At times empirical therapy can be given in sick children with suggestive symptoms or signs and chest radiograph abnormalities, with minimal or no improvement with a course of broad spectrum (nonfluoroquinolone) antibiotics. **(5)**

Studies comparing gastric lavage to induced sputum in adults with suspected tuberculosis reported induced sputum to be more effective. The aim of this study was to determine whether sputum induction can be successfully performed in children, to compare induced sputum with gastric lavage for the yield of M.tuberculosis in children with pulmonary tuberculosis and to analyse the clinico epidemiological profile, radiological features and outcome of children with smear positive pulmonary tuberculosis and presumptive cases started on antituberculosis treatment based on clinical and radiological non response after antibiotics.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

1. **Zar HJ, Hanslo D et al (6)** carried out a one year study in Cape Town, South Africa compared the yield of mycobacterium tuberculosis from repeated induced sputum samples with that from gastric lavage in young children from an area with a high rate of HIV and Tuberculosis .250 children with suspected Tuberculosis were studied, the median age being 13 months .A positive smear and culture obtained from 62 children (25%). Samples from induced sputum and gastric lavage were positive in 54 (87%) and 40 (65%) respectively. This study showed sputum induction was safe and preferable to gastric lavage in microbiological confirmation of pulmonary tuberculosis in infants and young children.

2. **K.B. Gupta and Seema Garg (2)** took one hundred cases of suspected pulmonary tuberculosis found smear negative during the period from January 2003 to December 2003 in the Department of Chest and Tuberculosis, PT. B.D. Sharma, Post Graduate Institute of Medical Sciences, Rohtak for the study. 97 patients produced adequate amount of sputum after hypertonic saline induction. 38 found positive for AFB on sputum microscopy after induction. And

concluded that sputum induction is a safe, simple and cost effective method of obtaining adequate amount of quality sputum in patients, who are smear negative on spontaneously produced sputum or are unable to produce sputum. Hypertonic saline induction products better quality and adequate sputum thereby increasing yield of smear positivity in pulmonary tuberculosis.

3. **Brown, Michael M et al (7)** recruited 140 consecutive adult in patients with chest radiography findings suggestive of tuberculosis who were unable to expectorate. 3 gastric washing specimens and at least 3 induced sputum specimens were performed in 107 subjects and 43% had cultures positive for Mycobacterium tuberculosis. Use of 3 induced sputum samples detected more cases than that of 3 gastric washings. They concluded that use of 3 induced sputum samples was more sensitive than use of 3 gastric washings for diagnosis of tuberculosis in patients who could not expectorate spontaneously and use of bronchoscopy with bronchoalveolar lavage did not increase diagnostic sensitivity

4. **Hatherill M, et al (8)** compared specimen collection methods for bacteriological confirmation of pulmonary tuberculosis were during a tuberculosis vaccine trial near Cape Town, South Africa (2001-2006). Children with a tuberculosis contact or compatible symptoms

were investigated for suspected pulmonary tuberculosis. Diagnostic yields from 764 paired induced sputum and gastric lavage specimens were compared in 191 culture confirmed cases. The comparative yield of a single induced sputum sample was equivalent to a single gastric lavage sample. The combined yield of same day induced sputum and gastric lavage specimens was equivalent to two consecutive gastric lavage specimens , but significantly greater than two consecutive gastric lavage specimens. They concluded that the diagnostic yield of a single induced sputum sample was equivalent to that of a single gastric lavage sample. The optimal diagnostic yield may be obtained from paired induced sputum and gastric lavage specimens taken on a single day or two gastric lavage specimens taken on consecutive days.

5. **David Bell et al (9)** retrospectively analysed 114 patients who had undergone the induced sputum procedure over one year period. They found that procedure was well tolerated with fewer side effects like nausea during the procedure and mild bronchospasm. None of the side effect was sufficient to stop the procedure. Patients with suspected pulmonary tuberculosis were referred for the induced sputum procedure and 12 patients who each underwent a single induced sputum procedure were found to have microbiologically

proven cases of pulmonary tuberculosis and of which 5 were smear positive pulmonary tuberculosis with a positive yield of 13.2%.Both the induced sputum procedure and gastric lavage are less invasive than is bronchoscopy and because fewer staff are involved, the risk of transmission of tuberculosis is likely to be less with the induced sputum procedure. Sputum induction does require a negative pressure room, but it can be done as a ward or outpatient procedure. They concluded that induced sputum procedure is a useful alternative for investigation of tuberculosis, with a positive yield similar to that achieved with gastric lavage.

6. **Moore H A, et al (10)** did a prospective study in a primary health care clinic in South Africa from April 2007 to June 2009. A total of 270 children were enrolled with median age of 38 months and sputum induction was successful in 99% of them; 24% children were clinically diagnosed, of whom 16.9% were microbiologically confirmed. An additional 18 children not clinically diagnosed had microbiological confirmation of pulmonary tuberculosis and were placed on tuberculosis treatment thereafter; increasing the diagnostic yield by 21.6%.They concluded that sputum induction is feasible and safe was useful for making a microbiological diagnosis, increasing

the number of children diagnosed and treated for pulmonary tuberculosis.

7. **A MA Shata, et al (11)** did induction of sputum by nebulised hypertonic saline (3%) was attempted in 30 Malawian children aged 3 to 15 years and was successful in 29. Four sputa were smear positive and Mycobacterium tuberculosis was cultured from three of them. A further four sputa were culture positive though smear negative. The diagnosis of tuberculosis was confirmed in eight (28%) of 29 children. They concluded that sputum induction is a useful method for the confirmation of tuberculosis and is possible in young children.

8. **H J Zar et al (12)** compared diagnostic yield of induced sputum with that of gastric lavage in microbiological confirmation of tuberculosis in children infected and uninfected with HIV. 149 children admitted with acute pneumonia and known to be infected with HIV were enrolled for the one year prospective study done in 1998. Sputum induction was successfully done in majority of the children and M.tuberculosis was cultured in 16 children. Culture was positive in 15 children in sample obtained from induced sputum. Gastric lavage was positive in nine and in eight of these M tuberculosis also grew from induced sputum. The difference in

mycobacterial yield from induced sputum compared to gastric lavage was 4.3% which was not statistically significant. M.tuberculosis was cultured in 10 of 100 HIV infected children compared to six of 42 HIV uninfected children which also was not statistically significant. They concluded that sputum induction can be safely and effectively performed in infants and young children. Induced sputum provides a satisfactory and specimen for bacteriological confirmation of pulmonary tuberculosis in HIV infected and uninfected children.

9. **Dick Menzies, et al (13)** reported a remarkably high yield of mycobacterial culture in a single specimen of induced sputum in 84 patients with tuberculous pleural effusions. Mycobacterial cultures were positive in induced sputum specimens from 44 (52%) patients compared with 10 (12%) pleural fluid specimens and 52 (62%) pleural biopsies. Induced sputum specimens provided bacteriologic confirmation in 55% of patients with normal lung parenchyma on chest X-ray, and the yield of sputum induction was independent of HIV status. They concluded that yield of induced sputum is high, but a major drawback is the delay in confirmation. In patients where TB is strongly suspected, clinicians should consider sputum induction for the initial investigation of undiagnosed pleural effusions.

10. **Jones FL (14)** ascertained the relative efficacy of three techniques widely used for collection of pulmonary secretions for bacteriological study in 155 patients with active pulmonary tuberculosis. Tubercle bacilli were recovered by cultures of specimens of spontaneously produced sputum, aerosol induced sputum, or gastric aspirates in 122 patients (79%). In 70 patients (45%), the ideally simple technique of spontaneously produced sputum was adequate for bacteriological diagnosis. Cultures of gastric aspirates and induced sputa greatly increased the yield of positive cultures in the remaining patients, being positive in 52 additional patients (34%).When results obtained with gastric aspirates were compared with those obtained with induced sputa, the latter technique was significantly superior. They concluded that in those without a productive cough the heated aerosol technique for sputum induction is clearly preferable to gastric aspiration in the bacteriological diagnosis of pulmonary tuberculosis.

STUDY JUSTIFICATION

STUDY JUSTIFICATION

- Bacteriological yield in childhood tuberculosis is very less when compared to adult tuberculosis due many constraints like age of the child (young children could not cough out sputum), type of collection (overnight fasting for gastric lavage) and specialized techniques (Bronchoalveolar lavage).

- Recent studies have shown that sputum induction is relatively easy, well tolerated and gives higher bacteriological yield.

- Since paramedical staffs are involved in collection of gastric lavage it may be one of the reason for low smear positivity

AIM OF THE STUDY

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Primary objective

To compare the smear positivity rate of specimen obtained from sputum induction and gastric lavage in the study population.

Secondary objective

To analyse the Clinico epidemiological profile and radiological features of children with pulmonary tuberculosis

SUBJECTS AND METHODS

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Methodology

Study design

Descriptive study (Evaluation of diagnostic test)

Study place

General medical wards and Department of Pulmonology, Institute of child health and hospital for children

Study period

December 2009 to September 2011.

Study population

Children who were considered as pulmonary tuberculosis suspects as per case definition, inclusion and exclusion criteria; admitted in general medical ward and Department of Pulmonology, institute of child health and hospital for children.

Case definition

Suspects of pulmonary tuberculosis included were children presenting with fever and / or cough for more than 2 weeks, with or without weight loss or no weight gain as per RNTCP guidelines.

Inclusion criteria

Children with suspected Pulmonary Tuberculosis with any one of the following criteria were included in the study

1. Chest radiography with parenchymal infiltrate or pneumonia or atelectasis, or intrathoracic lymphadenopathy
2. Positive Mantoux test which is taken as 10 mm or more induration at 48-72 hours following 1 TU of PPD given intradermally
3. History of contact with an adult who is diagnosed as tuberculosis or on antituberculosis treatment in the last two years.

Exclusion criteria

1. Children who already received antituberculosis treatment.
2. Children with severe respiratory distress (SpO2<92%).
3. Intubated patients, children with reduced level of consciousness.
4. Children with haemoptysis and unstable cardiovascular status.

5. Children with signs of upper airway obstruction

Sample size

As observed from other studies with smear positivity of gastric lavage as 10% and that of induced sputum as 19% with 5% alpha error and 20% beta error the calculated sample size was 254. 255 children were subjected for gastric aspirate and induced sputum technique on 2 consecutive days

Sampling technique

All Consecutive samples satisfying inclusion and exclusion criteria were included in the study.

Ethics

Written informed consent was obtained from the parents and Institution review board clearance was obtained

Maneuver

Children were enrolled if they had been admitted for suspected pulmonary tuberculosis on the basis of a chronic cough (more than 2 weeks) and/ or fever for more than 2 weeks with or without loss of weight or failure to gain weight within the previous 2 weeks; with any one of the following criteria: household contact known to be infected with tuberculosis within the previous 2 years; positive skin test to purified

protein derivative (1 TU), or chest radiography with parenchymal infiltrate, atelectasis, pleural effusion, or lymphadenopathy. Children were excluded if they were taking treatment for tuberculosis, had completed such treatment in the past, had signs of upper airway obstruction or had oxygen saturation less than 92% in room air. Written, informed consent for enrolment was obtained from a parent or legal guardian. The study was approved by the Research and Ethics Committee.

A history was taken and physical examination done. Baseline arterial pulse oximetry was undertaken in all children; monitoring was done throughout the sputum induction procedures and for 30 min thereafter. Children were clinically monitored for the duration of their stay in hospital. Smear positive tuberculosis was diagnosed when a stain for acid-fast bacilli was positive from induced sputum or gastric lavage specimens. Some smear negative children with either a positive contact or Mantoux test were presumptively started on anti tuberculosis treatment by the pulmonologist based on clinical and radiological non response even after course of antibiotics if pulmonary tuberculosis is strongly suspected. Analysis of the clinico epidemiological and radiological features of children with pulmonary tuberculosis started on antituberculosis treatment was done.

Sputum induction

Sputum induction is a procedure in which patient inhales nebulised hypertonic saline solution, which liquefies airway secretions, promotes coughing and allows expectoration of respiratory secretions. The procedure produces cough so it is likely that infectious droplets to be expelled into the room air so strict airborne respiratory precautions were observed whenever sputum induction is performed. **(3)**

Precautions

1. As hypertonic saline causes bronchoconstriction, the procedure was performed after pre-medication with salbutamol and under medical supervision in patients with asthma.

2. As the procedure causes cough the procedure was not be performed in patients in whom cough may be harmful. This included patients with:
    - haemoptysis of unknown origin
    - acute respiratory distress
    - unstable cardiovascular status
    - hypoxia (SaO_2 less than 92% on room air)

Infection control

1. Induction of sputum was conducted in an isolated room with good ventilation system.

2. Was performed under strict infection control measures by using face mask and disposable gloves.
3. Face mask was also used for the bystanders during the procedure.

Procedure

- A brief description of the procedure was explained to the parents.
- Sputum induction was undertaken after a 2 to 3 hour fast.
- The possible side effects to the patient like coughing, dry mouth, nausea and excess salivation were explained to the parents.
- Children were pretreated with 200 μg salbutamol nebulisation to prevent bronchoconstriction.
- The reservoir device of the nebuliser was filled with 5 ml of 3% hypertonic saline solution
- All subjects were asked to inhale a mist of 3% hypertonic saline solution delivered by nebuliser.
- Three to five milliliters of hypertonic saline (3%) was sufficient to induce sputum and 5-10 minutes nebulisation was adequate.
- The patient is instructed to inhale and exhale through the mouthpiece only and expectorate saliva in the emesis bowl and expectorate sputum coughed up into the sterile container if they can spontaneously expectorate.

- Thereafter, chest percussion was done over the anterior and posterior chest wall.
- The sputum was obtained by suctioning through the nasopharynx with a sterile mucus extractor of catheter size 6 or 7 in those who did not spontaneously expectorate.
- The sputum sample was collected in a clean sterile container.
- Patients were observed closely at all times during the procedure for signs of respiratory distress.
- The patient's condition was assessed post procedure, and appropriate action taken if required.
- The nebuliser chamber and mask removed and washed in water and dried and then wiped with spirit.
- The specimen was despatched immediately to RNTCP cell in tuberculosis clinic for acid fast bacilli staining.

Figure 1: a) 3% hypertonic saline nebulisation given. b) Collection of sputum with mucous extractor in young children.

Gastric lavage

Children with tuberculosis usually swallow mucus which contains M.tuberculosis. Gastric lavage is a technique used to collect gastric contents to try to confirm the diagnosis of tuberculosis by microscopy and mycobacterial culture. Because of the distress caused to the child, and the generally low yield of smear-positivity on microscopy, this procedure should only be used where culture is available as well as microscopy.

Mechanism

During sleep, the lung's mucociliary system beats mucus up into the throat. The mucus is swallowed and remains in the stomach until the stomach empties. Therefore, the highest-yield specimens are obtained first in the morning.

Advantage

Gastric aspiration is generally not an aerosol-generating procedure. As young children are also at low risk of transmitting infection, gastric aspiration can be considered a low risk procedure for tuberculosis transmission and can safely be performed at the child's bedside or in a routine procedure room.

Precautions

Children not fasting for at least 4 hours (3 hours for infants) prior to the procedure and children with a low platelet count or bleeding tendency should not undergo the procedure.

Method of gastric lavage

- A brief description of the procedure was explained to the parents.
- Children underwent early morning gastric lavage after an overnight fast; the first lavage was done the day after enrolment.
- The distance between the nose and stomach was measured to estimate distance that will be required to insert the tube into the stomach.
- The nasogastric tube through the nose and advanced into the stomach.
- The position of the tube was checked by pushing some air from the syringe into the stomach and listening with a stethoscope over the stomach.
- Gastric contents withdrawn using the syringe attached to the nasogastric tube.If the aspirate was less than 20 ml, 20 ml of normal saline was inserted down the tube, left for 2 to 3 min, and then aspirated. Additional 5 to10 ml samples of normal saline were inserted and aspirated until a minimum of 20 ml of aspirate was obtained.

- The specimen was despatched immediately to RNTCP cell in tuberculosis clinic for acid fast bacilli staining.

Figure 2: Collection of resting gastric juice by gastric lavage

Sputum obtained from sputum induction, gastric aspirate from cases selected for study on two consecutive days and specimens were sent for smear for acid fast bacilli staining. Smear positivity rate of the two procedures were compared. The reports were immediately informed to the attending physician to initiate appropriate treatment.

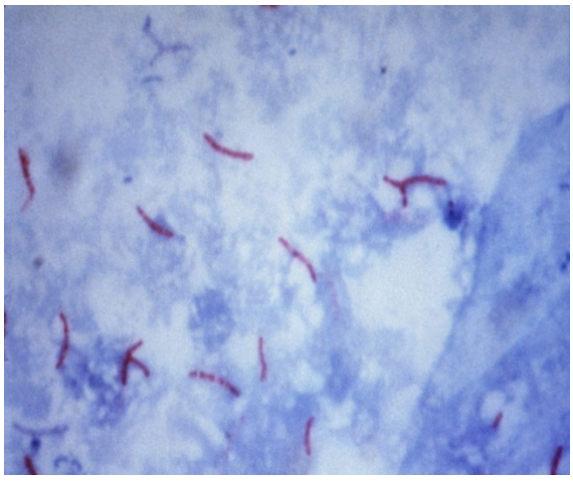


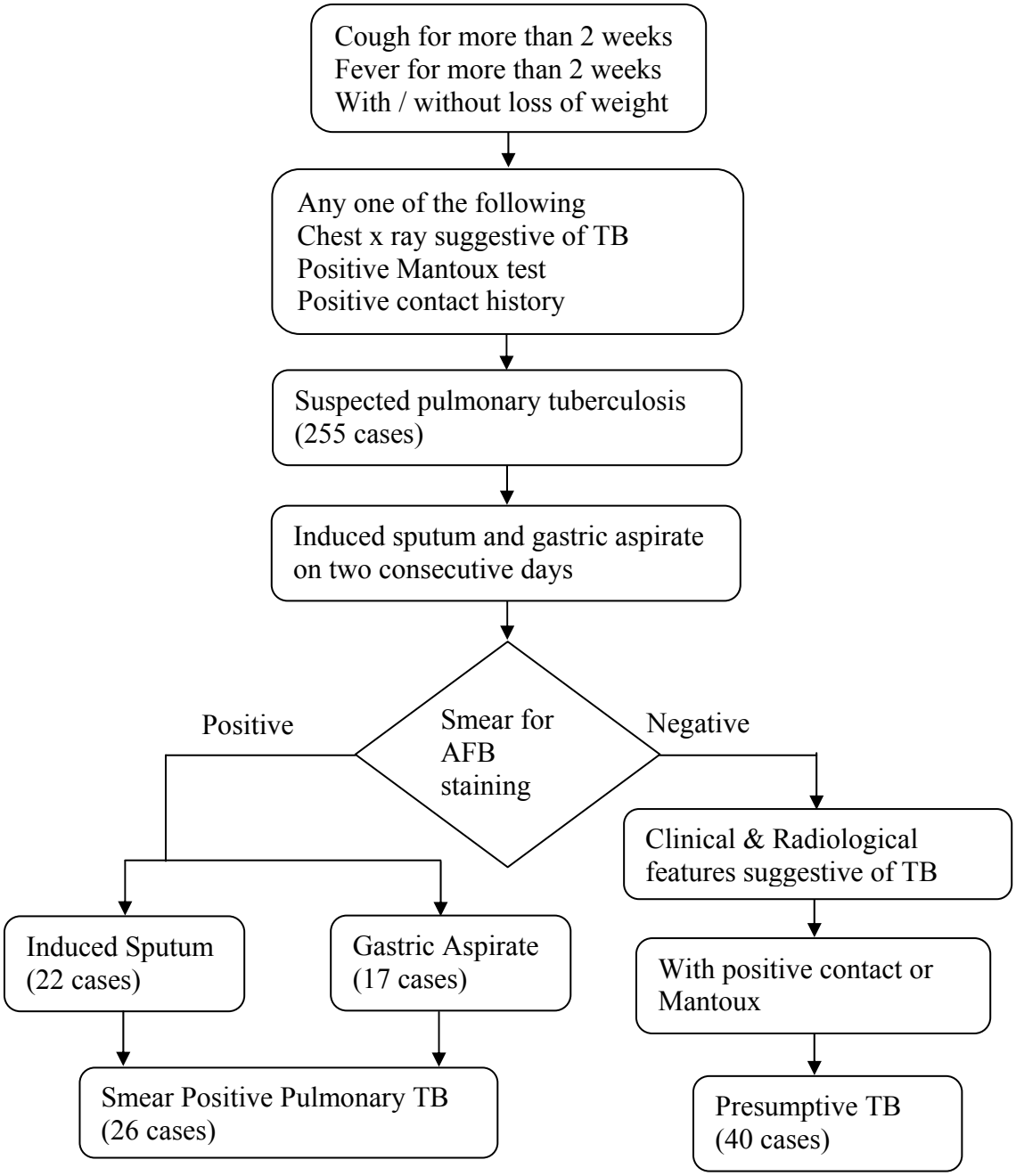
Figure 3: Ziehl Neelsen staining showing acid fast bacilli.

Statistical analysis

As observed from other studies with smear positivity of gastric lavage as 10% and that of induced sputum as 19% with 5% alpha error and 20% beta error the calculated sample size was 254.Stastical analysis done using SPSS version 17.0.

Univariate analysis was done using chi square test. By taking all significant variables from Univariate analysis binary logistic regression was done. Two procedures compared by epi version 2.

Algorithm of the study methodology



RESULTS

RESULTS

255 children with suspected pulmonary tuberculosis underwent sputum induction and gastric lavage for two consecutive days after enrollment; 146 (57%) were male and 109(43%) were female.230 children had adequate sputum on induction and additional 20 children had adequate sputum on repeat nebulisation after 30 minutes and 5 children sputum was inadequate. No serious adverse reactions attributable to sputum induction occurred during or after the procedure; the most common adverse events noted were an increase in coughing in 5 cases (2%), vomiting in 6 cases (2.3%) and none had epistaxis or wheezing.

Out of the 255 suspected pulmonary tuberculosis cases included in the study 66 cases were started on anti tuberculosis treatment which includes both smear positive and presumptive group.

Of the 66 cases, 26 cases (39%) were smear positive and 40 cases(61%) were smear negative but presumptively started on antituberculosis treatment by pulmonologist on the basis of clinical and persistent radiological abnormalities and with a positive contact or mantoux test and they improved with antituberculosis treatment.

The epidemiological features, clinical symptoms and signs, contact and mantoux positivity, radiological features of the cases started on anti

tuberculosis treatment who were categorised into smear positive group (26 cases) and presumptive tuberculosis group(40 cases) and comparison of the above parameters between the two groups was done.

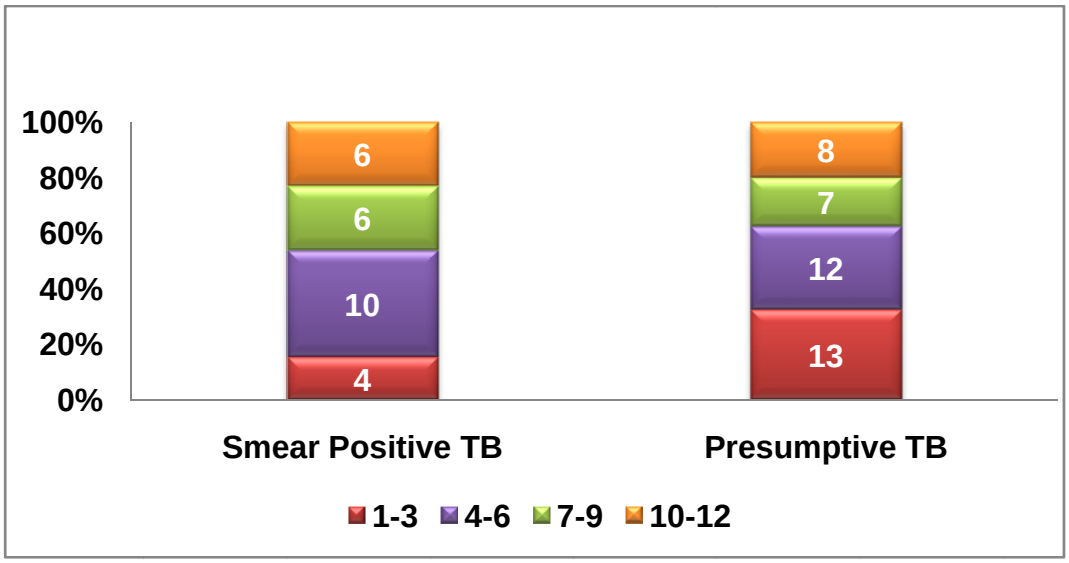


Figure 4: Comparison of age distribution of smear positive and presumptive TB cases

No statistically significant age predilections noted in either smear positive or presumptive tuberculosis cases.

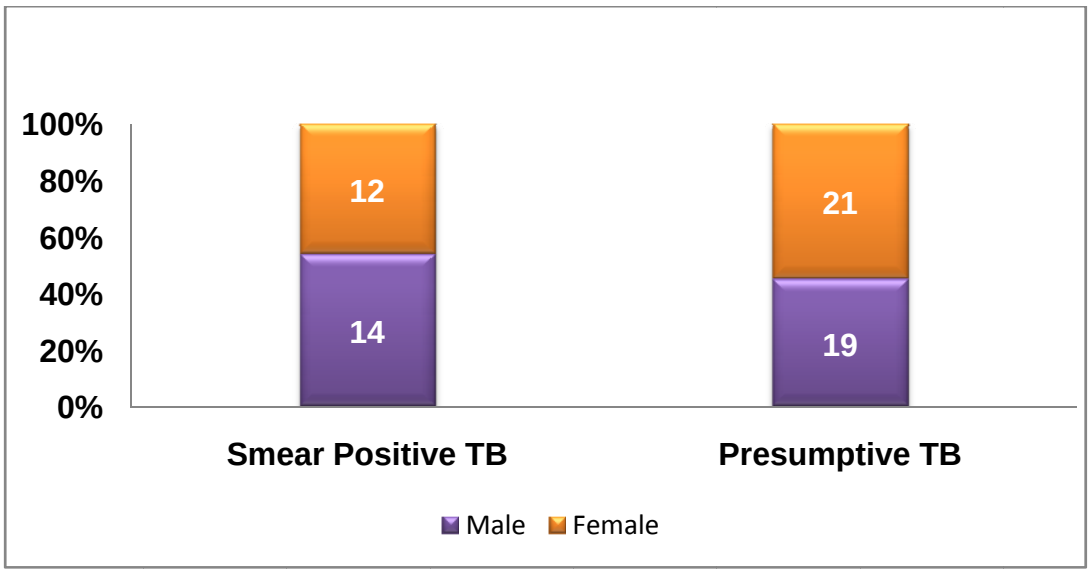


Figure 5: Comparison of gender distribution of smear positive and presumptive TB cases

No gender wise variations noted in either smear positive or presumptive tuberculosis cases.

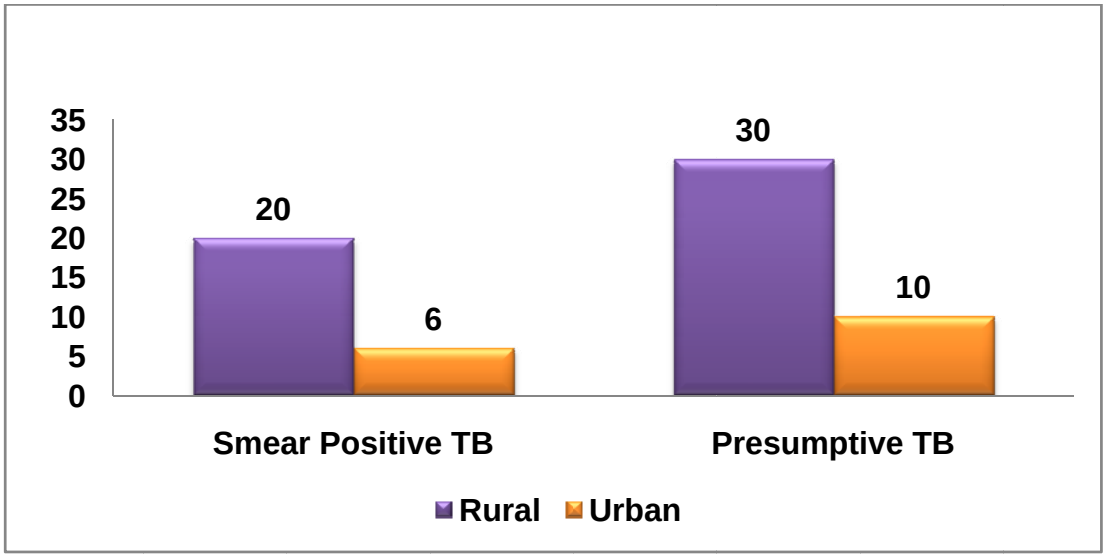


Figure 6: Comparison of rural-urban distribution of smear positive and presumptive TB cases

In both smear positive and presumptive group majority were from rural population.

- Of the 66 cases started on anti tuberculosis treatment, all age groups are equally affected, 1-3 years- 17(26%); 4-6 years-22(33%); 7-9 years-13(20%); 10-12 years-14(21%). Among them no age predilections noted in either smear positive or presumptive tuberculosis cases.
- Sex distribution of 66 cases started on anti tuberculosis treatment was similar. In smear positive group 14(53.8%) were male and 12(46.2%) were female which was similar to the presumptive tuberculosis group where 19(47.5%) were male and 21(52.5%) were female.
- Of the 66 cases started on anti tuberculosis treatment, 50(75.8%) were from rural and 16(24.2%) were from urban population. In smear positive group 20(76.9%) were from rural population which was similar to that in the presumptive tuberculosis group (75%).

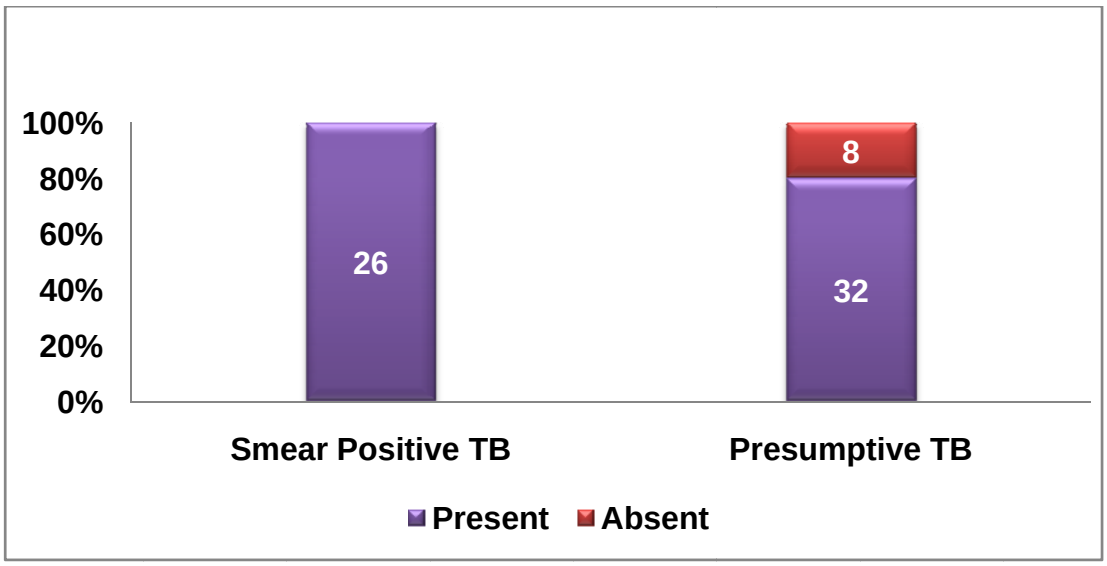


Figure 7: Comparison of cough for more than 2 weeks in smear positive and presumptive TB cases

Cough for more than two weeks was present in all 26(100%) smear positive cases and in 32(80%) of presumptive tuberculosis cases

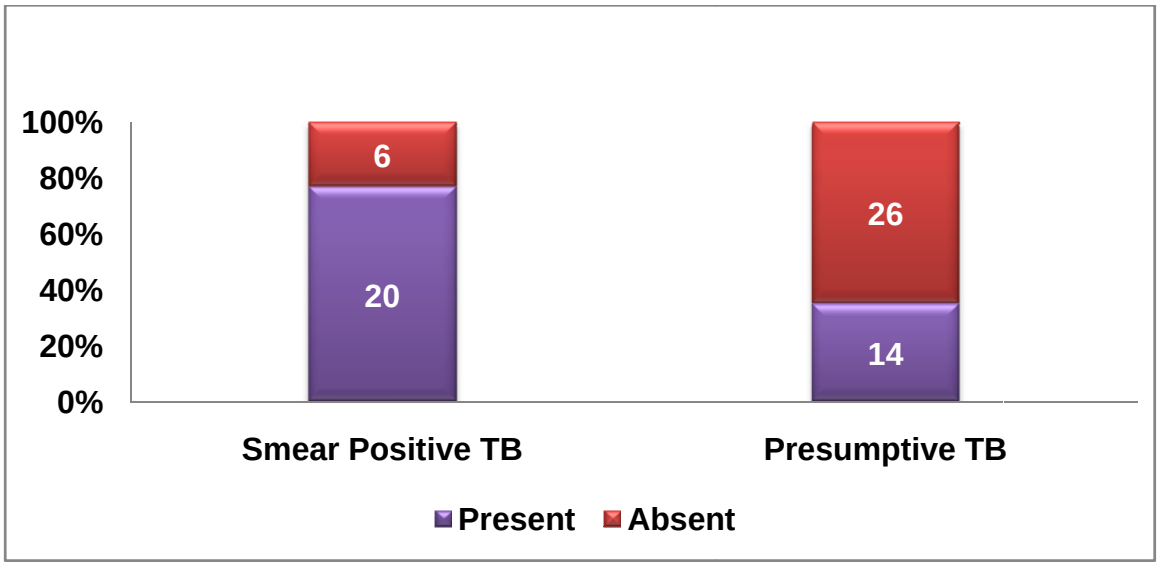


Figure 8: Comparison of fever for more than 2 weeks in smear positive and presumptive TB cases

Fever for more than two weeks was present in 20(76.9%) smear positive cases which were higher than in presumptive tuberculosis cases 14(35%).

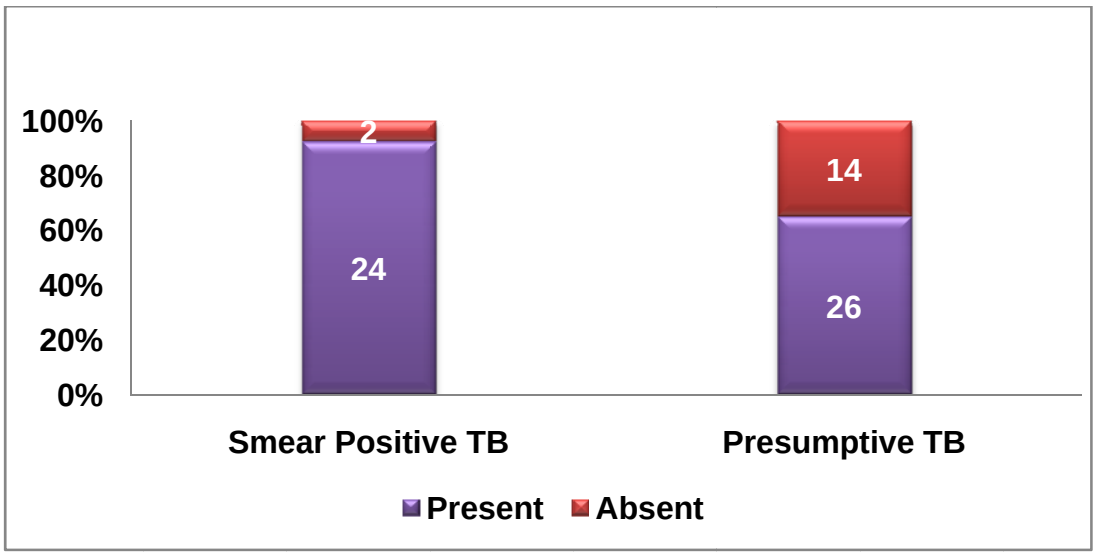


Figure 9: Comparison of loss of weight in smear positive and presumptive TB cases

Loss of weight was present in 24(92.3%) smear positive cases and 26(65%) of presumptive tuberculosis cases.

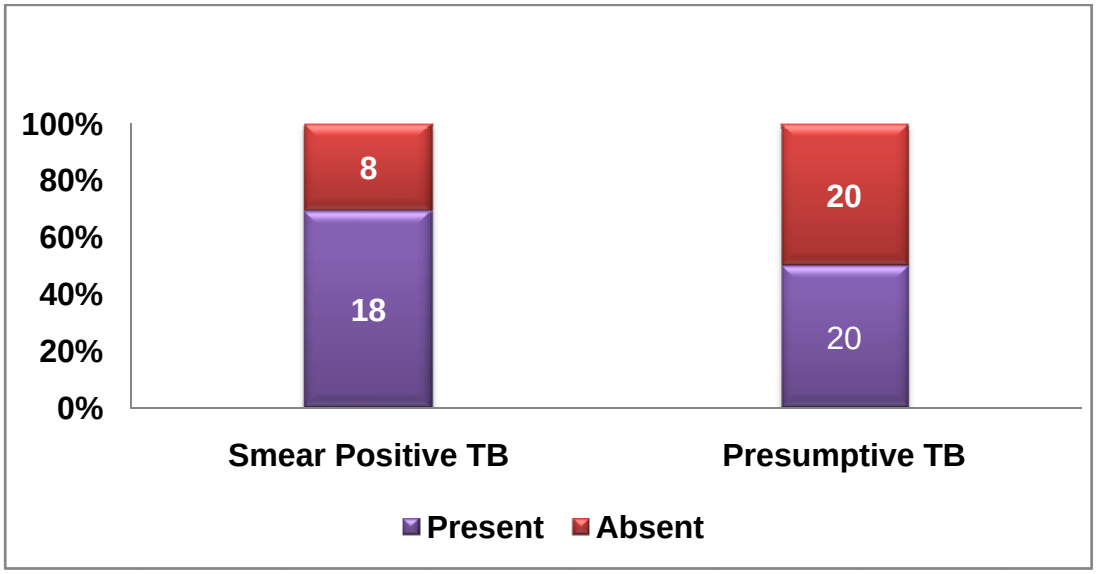


Figure 10: Comparison of breathlessness in smear positive and presumptive TB cases

Breathlessness was present in 18(69.2%) smear positive cases and 20(50%) of presumptive tuberculosis cases.

- Cough for more than two weeks was present in all 26(100%) smear positive cases and in 32(80%) of presumptive tuberculosis cases (**p value=.052**) .Cough for more than two weeks was present in 58 (87.9%) of 66 cases started on anti tuberculosis treatment.
- Fever for more than two weeks was present in 20(76.9%) smear positive cases which was higher than in presumptive tuberculosis cases 14(35%) (**p value=.000<.001**). Fever for more than two weeks was present in 34(51.5%) of 66 cases started on anti tuberculosis treatment.
- Loss of weight was present in 24(92.3%) smear positive cases which was higher than in presumptive tuberculosis cases 26 (65%) (**p value=.000<.001**). Loss of weight was present in 50(75.8%) of 66 cases started on anti tuberculosis treatment.
- Breathlessness was present in 18(69.2%) smear positive cases and 20(50%) of presumptive tuberculosis cases (**p value=.000<.001**). Breathlessness was noted in 38(50.7%) of 66 cases started on anti tuberculosis treatment.

Table 1: Comparison of symptoms of smear positive tuberculosis and presumptive tuberculosis cases

Symptom	**Smear positive tuberculosis** **n=26**	**Presumptive tuberculosis** **n=40**	**P value**
Cough >2wk	26 (100)	32 (80)	.052
Fever >2wk	20 (76.9)	14 (35)	.000<.001
Breathlessness	18 (69.2)	20 (50)	.000<.001
Loss of weight	24 (92.3)	26 (65)	.000<.001

Fever for more than 2 weeks, breathlessness and loss of weight was higher in smear positive group compared to presumptive tuberculosis which was statistically significant.

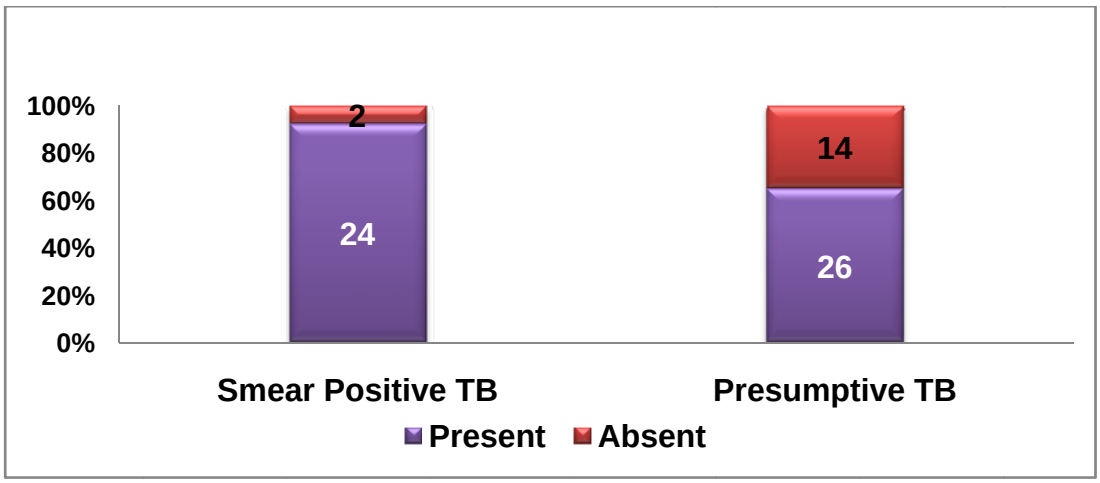


Figure 11: Comparison of under nutrition in smear positive and presumptive TB cases

Under nutrition was present in 24(92.3%) smear positive cases and 26(65%) of presumptive tuberculosis cases.

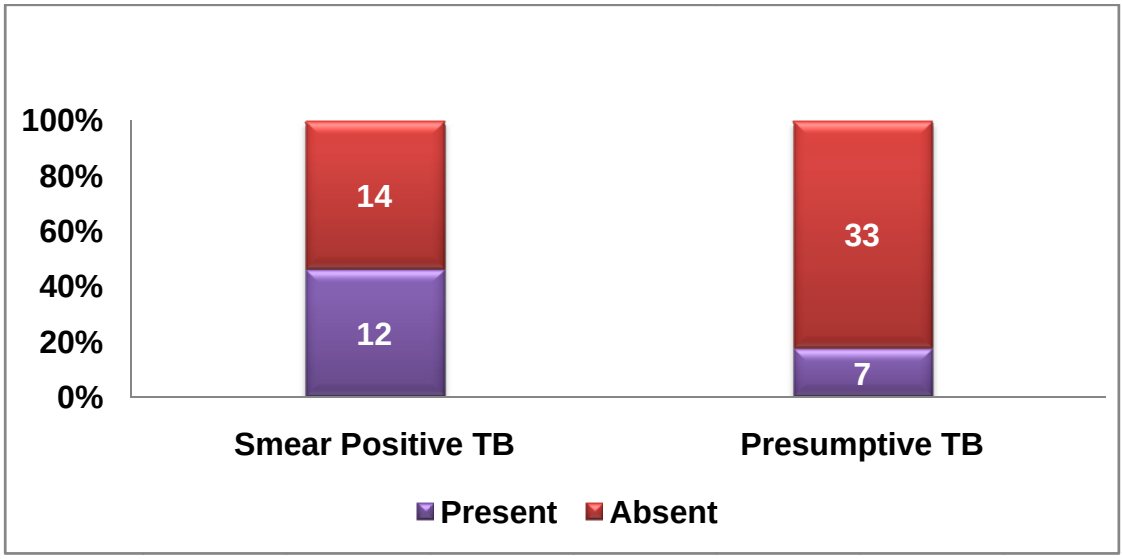


Figure 12: Comparison of pallor in smear positive and presumptive TB cases

Pallor was observed in 12(46.2%) smear positive cases and 7(17.5%) of presumptive tuberculosis cases.

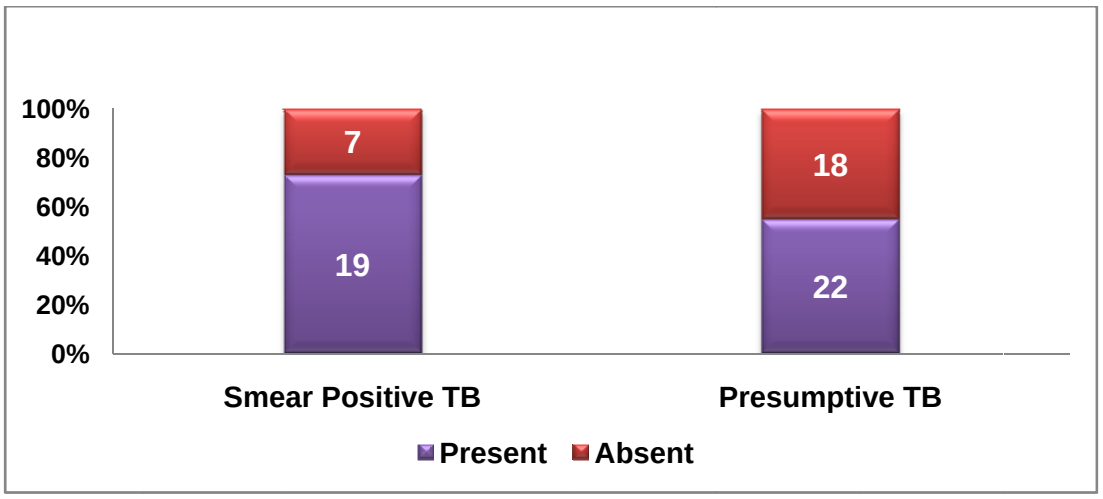


Figure 13: Comparison of lung signs in smear positive and presumptive TB cases

Clinically lung signs in the form of crepitations present in 19(73.1%) smear positive cases and 22(55%) of presumptive tuberculosis cases.

- Under nutrition was present in 24(92.3%) smear positive cases which was higher than in presumptive tuberculosis cases 26 (65%) (**p value=.000<.001**). 50(75.8%) of 66 cases started on antituberculosis treatment were undernourished.
- Pallor was observed in 12(46.2%) smear positive cases which was higher than in presumptive tuberculosis cases 7 (17.5%) (**p value=.000<.001**). 19(28.8%) of 66 cases started on anti tuberculosis treatment had pallor.
- Clinically lung signs in the form of crepitations present in 41(62.1%) %) of 66 cases started on anti tuberculosis treatment, in 19(73.1%) smear positive cases and 22(55%) of presumptive tuberculosis cases.9 cases (22.5%) of presumptive tuberculosis group had reduced air entry.

Table 2: Comparison of signs of smear positive tuberculosis and presumptive tuberculosis cases

Signs	**Smear positive tuberculosis n=26**	**Presumptive tuberculosis n=40**	**P value**
Undernutrtion	24 (92.3)	26 (65)	.000<.001
Pallor	12 (46.2)	7 (17.5)	.000<.001
Added sounds	19 (73.1)	22 (55)	.000<.001

Pallor, under nutrition and lung signs were higher in smear positive tuberculosis cases compared to presumptive tuberculosis cases which was statistically significant.

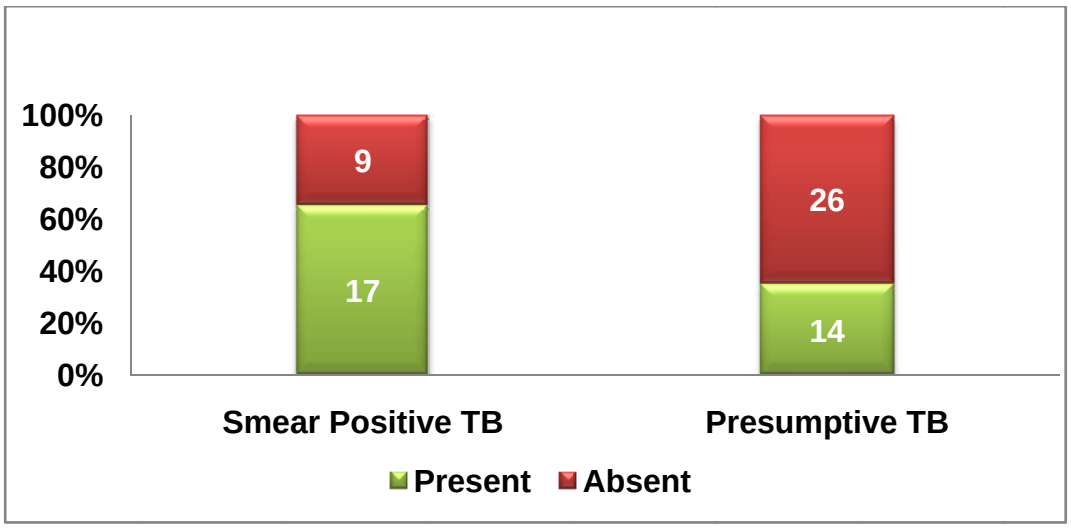


Figure 14: Comparison of contact with tuberculosis in smear positive and presumptive TB cases

Contact with tuberculosis was higher in 17(65.4%) smear positive compared to presumptive tuberculosis cases 14(35%).

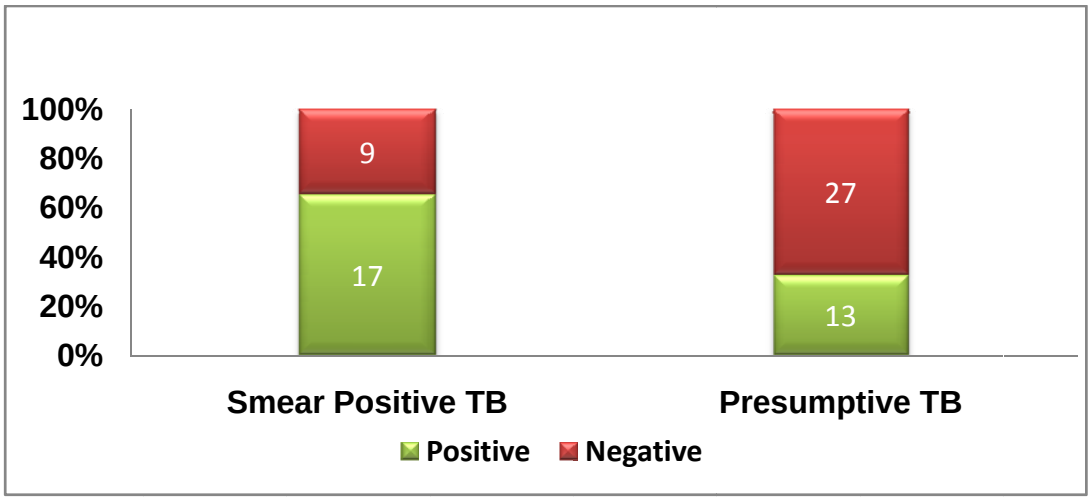


Figure 15: Comparison of Mantoux test in smear positive and presumptive TB cases

Mantoux positivity was higher in smear positive17 (65.4%) compared to presumptive tuberculosis cases13 (32.5%).

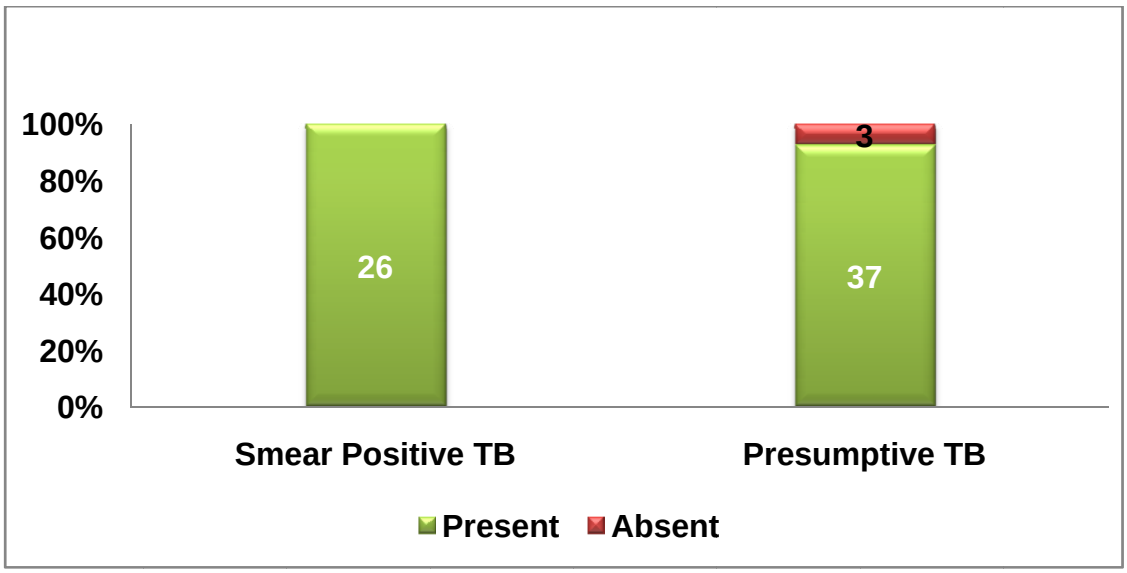


Figure 16: Comparison of chest x ray lesion in smear positive and presumptive TB cases

Radiological lesions in lung was present in all 26(100%) smear positive cases and 37(92.5%) of presumptive tuberculosis cases.

- Contact with tuberculosis was present in 17(65.4%) smear positive cases which was higher than in presumptive tuberculosis cases 14 (35%) (**p value=.01**) . Contact with tuberculosis was present in 31(47%) of 66 cases started on anti tuberculosis treatment.
- Mantoux test was positive in 17(65.4%) smear positive cases which was higher than in presumptive tuberculosis cases13 (32.5%) (**p value=.02**). Mantoux test was positive in 30(45.5%) of 66 cases started on anti tuberculosis treatment.
- Radiological lesions in lung was present in all 26(100%) smear positive cases which was higher than in presumptive tuberculosis cases 37(92.5%) (**p value=.000<.001**). 63(95.5%) of 66 cases started on anti tuberculosis treatment had radiological lesions in lung. Pneumonia was the commonest radiological finding (68%) followed by bronchiectasis (9%), collapse (7%), pleural effusion (6%) and intrathoracic adenopathy (3%).

Table 3: Contact, mantoux positivity and chest x ray lesion of smear positive tuberculosis and presumptive tuberculosis cases

Parameter	Smear positive tuberculosis n=26	Presumptive tuberculosis n=40	P value
Contact with tuberculosis	17 (65.4)	14 (35)	.01
Mantoux positive	17 (65.4)	13 (32.5)	.02
Chest x ray lesion	26 (100)	37 (92.5)	.000<.001

Contact, mantoux positivity and chest X ray lesion were higher in smear positive tuberculosis cases compared to presumptive tuberculosis cases which were statistically significant.

All significant factors from Univariate analysis of symptoms, signs, contact positivity, mantoux positivity and chest x ray positivity were taken for binary logistic regression model and found that loss of weight, chest x ray lesion and mantoux positivity were significant triad of risk factors for pulmonary tuberculosis.

Table 4: Binary logistic regression model

Parameter	Significance	Odds ratio
Loss of weight	0.016	2.601
Chest x ray lesion	.000<.001	17.698
Mantoux positivity	.007	2.983

- Of the children with suspected pulmonary tuberculosis subjected to sputum induction and gastric lavage, induced sputum was smear positive in 22 cases and gastric lavage was smear positive in 17 cases.
- M .tuberculosis was identified from the first sample of induced sputum in 21 (32%) children; second sample yielded an additional one case, increasing diagnostic yield by 1%.
- Both induced sputum and gastric lavage was smear positive in 13 cases.
- Combining both procedures the overall smear positive cases were 26 (39%).
- Of the 26 smear positive cases, 9 more identified from induced sputum than gastric lavage with difference in yield of 13.6% and gastric lavage identified 4 more smear positive cases where induced sputum was negative with difference in yield of 6.1%.

The diagnostic accuracy of induced sputum compared with gastric lavage taking smear for acid fast bacilli as reference test

Induced sputum against the reference test smear for acid fast staining

Test	Smear for AFB positive	Smear for AFB negative	Total
Induced sputum Positive	22	0	22
Induced sputum negative	4	229	233
Total	26	229	255

Parameter	Estimate	Lower - Upper 95% CIs
Sensitivity	**84.62%**	(66.47, 93.85[1])
Specificity	**100%**	(98.35, 100[1])
Positive Predictive Value	**100%**	(85.13, 100[1])
Negative Predictive Value	**98.28%**	(95.67, 99.33[1])
Diagnostic Accuracy	**98.43%**	(96.04, 99.39[1])

Gastric lavage against the reference test smear for acid fast staining

Test	Smear for AFB positive	Smear for AFB negative	Total
Gastric lavage Positive	17	0	17
Gastric lavage negative	9	229	238
Total	26	229	255

Parameter	Estimate	Lower - Upper 95% CIs
Sensitivity	65.38%	(46.22, 80.59[1])
Specificity	100%	(98.35, 100[1])
Positive Predictive Value	100%	(81.57, 100[1])
Negative Predictive Value	96.22%	(92.97, 98[1])
Diagnostic Accuracy	96.47%	(93.43, 98.13[1])

Induced sputum (84.62%) had a higher sensitivity compared to gastric lavage (65.38%), and negative predictive value of induced sputum (98.28%) was higher than gastric lavage (96.22%). Specificity and positive predictive value of both procedures were 100%. Induced sputum (98.43%) had a higher diagnostic accuracy than gastric lavage (96.47%).

Since culture was not feasible for all 255 cases smear and presumptive cases were taken as gold standard and diagnostic accuracy of induced sputum compared with gastric lavage.

Induced sputum against the reference test smear and presumptive cases

Test	Smear and presumptive positive	Smear and presumptive negative	Total
Induced sputum Positive	22	0	22
Induced sputum negative	44	189	233
Total	66	189	255

Parameter	Estimate	Lower - Upper 95% CIs
Sensitivity	33.33%	(23.16, 45.34[1])
Specificity	100%	(98.01, 100[1])
Positive Predictive Value	100%	(85.13, 100[1])
Negative Predictive Value	81.12%	(75.6, 85.62[1])
Diagnostic Accuracy	82.75%	(77.63, 86.89[1])

Gastric lavage against the reference test smear and presumptive cases

Test	Smear and presumptive positive	Smear and presumptive negative	Total
Gastric lavage positive	17	0	17
Gastric lavage negative	49	189	238
Total	66	189	255

Parameter	Estimate	Lower - Upper 95% CIs
Sensitivity	25.76%	(16.75, 37.43[1])
Specificity	100%	(98.01, 100[1])
Positive Predictive Value	100%	(81.57, 100[1])
Negative Predictive Value	79.41%	(73.83, 84.06[1])
Diagnostic Accuracy	80.78%	(75.51, 85.15[1])

Induced sputum (33.33%) had a higher sensitivity compared to gastric lavage (25.76%), and negative predictive value of induced sputum (81.12%) was higher than gastric lavage (79.41%). Specificity and positive predictive value of both procedures were 100%. Induced sputum (82.75%) had a higher diagnostic accuracy than gastric lavage (80.78%).

Table 5: Comparison of induced sputum versus gastric lavage

Test	Gold standard or reference test	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)	Diagnostic accuracy (%)
Induced sputum	Smear for AFB	84.62	100	100	98.28	98.43
Gastric lavage	Smear for AFB	65.38	100	100	96.22	96.47
Induced sputum	Smear and presumptive	33.33	100	100	81.12	82.75
Gastric lavage	Smear and presumptive	25.76	100	100	79.4	80.78

Induced sputum had a higher sensitivity and negative predictive value than gastric lavage. Specificity and positive predictive value of both procedures are similar. Induced sputum had a higher diagnostic accuracy compared to gastric lavage.

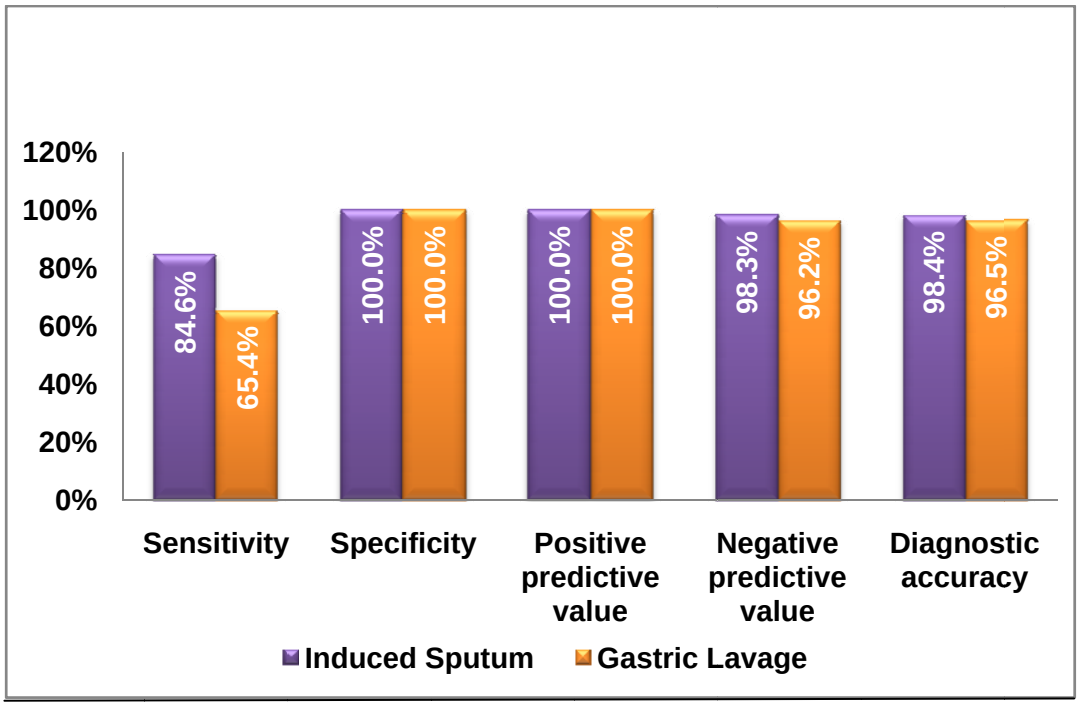


Figure 17: Induced sputum versus gastric lavage (smear for AFB as reference standard)

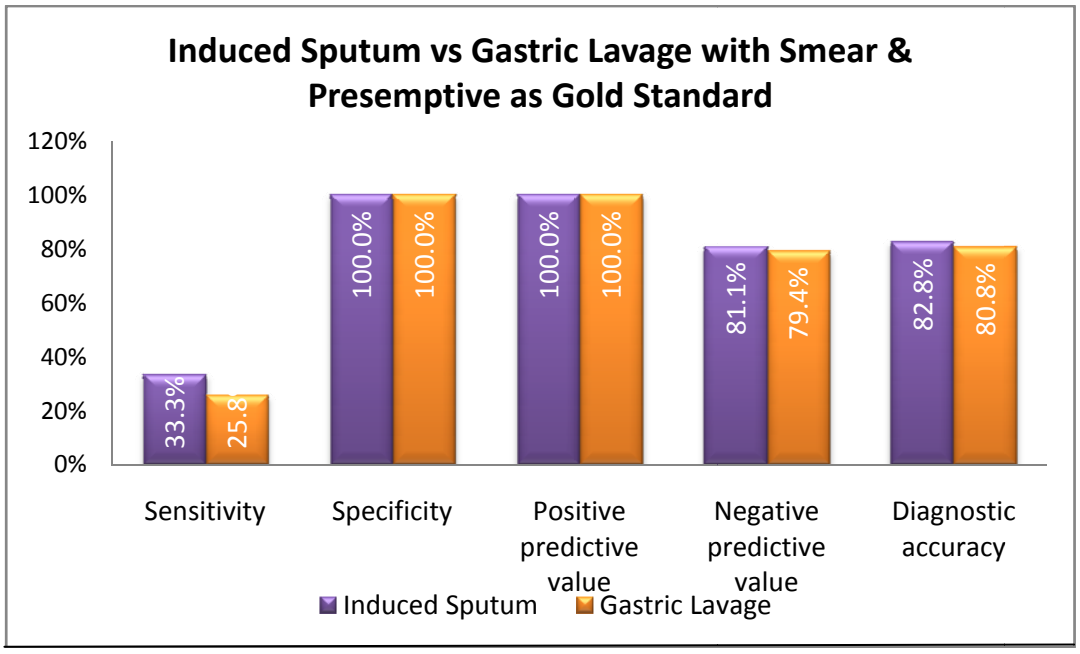


Figure 18: Induced sputum versus gastric lavage (smear positive and presumptive cases as reference test)

Table 6. Clinico – epidemiological, radiological features, smear positivity of gastric lavage and induced sputum in children with pulmonary tuberculosis (smear positive and presumptive cases started on antituberculosis treatment) n = 66

Age Gp In yrs	M	F	Cont +	MX+	Un	Pneum	Pleu	IT Lymp	Coll	B' ect	GL1 +	GL2 +	GL +	IS 1 +	IS 2 +	IS +
1-3 17 (26)	11 (17)	6 (9)	9 (14)	9 (14)	11 (17)	15 (23)	0 (0)	0 (0)	1 (1.5)	0 (0)	3 (5)	2 (3)	3 (5)	1 (1.5)	2 (3)	2 (3)
4-6 22 (33)	11 (17)	11 (17)	8 (12)	9 (14)	21 (32)	15 (23)	0 (0)	1 (1.5)	1 (1.5)	4 (6)	5 (8)	5 (8)	5 (8)	9 (14)	7 (11)	9 (12)
7-9 13 (20)	7 (11)	6 (9)	9 (14)	6 (9)	11 (17)	6 (9)	1 (1.5)	1 (1.5)	2 (3)	1 (1.5)	5 (8)	5 (8)	5 (8)	5 (8)	5 (8)	5 (8)
10-12 14 (21)	4 (6)	10 (15)	6 (9)	7 (11)	7 (11)	9 (14)	3 (4)	0 (0)	1 (1.5)	1 (1.5)	4 (6)	4 (6)	4 (6)	6 (9)	5 (8)	6 (9)
TOTAL 66 (100)	33 (50)	33 (50)	32 (48)	31 (47)	50 (76)	45 (68)	4 (6)	2 (3)	5 (7)	6 (9)	17 (26)	16 (24)	17 (26)	21 (32)	19 (29)	22 (33)

Percentage in parenthesis M= male; F= female
Cont+ = contact positive; MX+ = Mantoux positive; Un = undernourished.
Pneum = pneumonia; Pleu = pleural effusion; IT lymp = intra thoracic adenopathy
Coll = collapse; B' ect= bronchiectasis GL= gastric lavage; IS = induced sputum.
GL1=gastric lavage first sample; GL2= gastric lavage second sample; IS 1= induced sputum first sample; IS 2 = induced sputum second sample

Table 7. **Clinico epidemiological profile, radiological features and lung involvement in smear positive pulmonary tuberculosis**. n=26

Age Gp In yrs	M	F	Cont+	MX+	Un	pneum					Pleu	IT Lymp	Coll	B' ect
						Total	RT	LT	UL	LL				
1-3 4 (15)	4 (15)	0 (0)	3 (11)	3 (11)	4 (15)	3 (11)	2 (8)	1 (4)	0 (0)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)
4-6 10 (38)	6 (23)	4 (15)	7 (27)	6 (23)	10 (38)	7 (27)	3 (11)	1 (4)	1 (4)	5 (19)	0 (0)	1 (4)	1 (4)	1 (4)
7-9 6 (23)	2 (8)	4 (15)	4 (15)	4 (15)	6 (23)	5 (19)	1 (4)	2 (8)	1 (4)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)
10-12 6 (23)	2 (8)	4 (15)	3 (11)	4 (15)	6 (23)	6 (23)	3 (11)	2 (8)	1 (4)	2 (8)	1 (4)	0 (0)	1 (4)	0 (0)
TOTAL 26 (100)	14 (54)	12 (46)	17 (65)	17 (65)	26 (100)	21 (81)	9 (34)	6 (23)	3 (11)	9 (34)	1 (4)	1 (4)	2 (8)	1 (4)

Percentage in parenthesis
M= male; F= female
Cont+ = contact positive; MX+ = Mantoux positive; Un = undernourished.
Pneum = pneumonia; RT= right lung; LT= left lung; UL= upper lobe; LL= lower lobe
Pleu = pleural effusion; IT lymp = intra thoracic adenopathy
Coll = collapse; B' ect= bronchiectasis

Table 8. Radiological findings and lung involvement in smear positive pulmonary tuberculosis. n = 26

Age Gp In yrs	Pneum										cavity		B' ect		Coll		IT Lymp	
	Total		UL		LL		RT		LT									
	IS	GL	IS	GL	IS	GL	IS	GL	IS	GL	IS	GL	IS	GL	IS	GL	IS	GL
1 – 3 4 (15)	1 (4)	2 (8)	0 (0)	0 (0)	2 (8)	2 (8)	1 (4)	1 (4)	2 (8)	1 (4)	1 (4)	1 (4)	0 (0)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)
4 – 6 10 (38)	6 (23)	4 (15)	1 (4)	1 (4)	2 (8)	2 (8)	4 (15)	3 (11)	1 (4)	2 (8)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	0 (0)	1 (4)	0 (0)
7 - 9 6 (23)	3 (11)	3 (11)	1 (4)	0 (0)	3 (11)	3 (11)	1 (4)	1 (4)	1 (4)	1 (4)	2 (8)	2 (8)	1 (4)	2 (8)	0 (0)	0 (0)	0 (0)	0 (0)
10 -12 6 (23)	6 (23)	4 (15)	1 (4)	0 (0)	1 (4)	1 (4)	2 (8)	1 (4)	2 (8)	1 (4)	0 (0)	0 (0)	2 (8)	2 (8)	1 (4)	1 (4)	0 (0)	0 (0)
TOTAL 26 (100)	16 (62)	13 (50)	3 (11)	1 (4)	8 (31)	8 (31)	8 (31)	6 (23)	6 (23)	5 (19)	4 (15)	4 (15)	4 (15)	6 (23)	2 (8)	1 (4)	1 (4)	0 (0)

Percentage in parenthesis
Pneum = pneumonia; RT= right lung; LT= left lung; UL= upper lobe; LL= lower lobe
IS= induced sputum; GL= resting gastric juice;
Cavity= cavitatory lesions
Pleu = pleural effusion; IT lymp = intra thoracic adenopathy
Coll = collapse; B' ect= bronchiectasis

Table 9. Clinico epidemiological profile, radiological features and lung involvement in presumptive pulmonary tuberculosis. n=40

Age Gp In yrs	M	F	Cont +	MX+	Un	Pneum					Pleu	IT Lymp	Coll	B'ect
						Total	RT	LT	UL	LL				
1-3 13 (32)	6 (15)	7 (17)	6 (15)	6 (15)	9 (22)	10 (25)	7 (17)	3 (7)	3 (7)	4 (10)	0 (0)	1 (2)	1 (2)	0 (0)
4-6 12 (30)	6 (15)	6 (15)	2 (5)	3 (7)	12 (30)	7 (17)	5 (12)	2 (5)	1 (2)	4 (10)	0 (0)	0 (0)	1 (2)	2 (5)
7-9 7 (17)	4 (10)	3 (7)	4 (10)	2 (5)	6 (15)	3 (7)	2 (5)	3 (7)	1 (2)	3 (7)	1 (2)	1 (2)	1 (2)	1 (2)
10-12 8 (20)	2 (5)	6 (15)	3 (7)	3 (7)	3 (7)	3 (7)	4 (10)	3 (7)	1 (2)	2 (5)	2 (5)	0 (0)	1 (2)	1 (2)
Total 40 (100)	18 (45)	22 (55)	15 (37)	14 (35)	30 (75)	23 (57)	18 (45)	11 (27)	6 (15)	13 (32)	3 (7)	2 (5)	4 (10)	4 (10)

Percentage in parenthesis M= male; F= female
Cont+ = contact positive; MX+ = Mantoux positive; Un = undernourished.
Pneum = pneumonia; RT= right lung; LT= left lung; UL= upper lobe; LL= lower lobe
Pleu = pleural effusion; IT lymp = intra thoracic adenopathy
Coll = collapse; B' ect= bronchiectasis

Table 10. Comparison of Clinico epidemiological features of smear positive and presumptive pulmonary tuberculosis.

Age Gp In yrs	M		F		Cont +		MX+		Un	
	SP	PRES	SP	PRES	SP	PRES	SP	PRES	SP	PRES
1-3 17	4 (15)	6 (15)	0 (0)	7 (17)	3 (11)	6 (15)	3 (11)	6 (15)	4 (15)	9 (22)
4-6 22	6 (23)	6 (15)	4 (15)	6 (15)	7 (27)	2 (5)	6 (15)	3 (7)	10 (38)	12 (30)
7-9 13	2 (8)	4 (10)	4 (15)	3 (7)	4 (15)	4 (10)	4 (15)	2 (5)	6 (23)	6 (15)
10-12 14	2 (8)	2 (5)	4 (15)	6 (15)	3 (11)	3 (7)	4 (15)	3 (7)	6 (23)	3 (7)
Total 66	14 (54)	18 (45)	12 (46)	22 (55)	17 (65)	15 (37)	17 (65)	14 (35)	26 (100)	30 (75)

Percentage in parenthesis
SP= smear positive TB cases; PRES= presumptive TB cases
M= male; F= female
Cont+ = contact positive; MX+ = Mantoux positive; Un = undernourished

Table 11. Comparison of radiological features and lung involvement of smear positive with presumptive pulmonary tuberculosis

Age Gp In yrs	Pneum										Pleu		IT Lymp		Coll		B'ect	
	Total		RT		LT		UL		LL									
	SP	PRES	SP	PRES	SP	PRES	SP	PRES	SP	PRES	SP	PRES	SP	PRES	SP	PRES	SP	PRES
1-3 17	3 (11)	10 (25)	2 (8)	7 (14)	1 (4)	3 (7)	0 (0)	3 (7)	1 (4)	4 (10)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	1 (2)	0 (0)	0 (0)
4-6 22	7 (27)	7 (17)	2 (8)	5 (12)	1 (4)	2 (5)	1 (4)	1 (2)	4 (15)	4 (10)	0 (0)	0 (0)	1 (4)	0 (0)	1 (4)	1 (2)	1 (4)	2 (5)
7-9 13	5 (19)	3 (7)	1 (4)	2 (5)	2 (8)	3 (7)	1 (4)	1 (2)	1 (4)	3 (7)	0 (0)	1 (2)	0 (0)	1 (2)	0 (0)	1 (2)	0 (0)	1 (2)
10-12 14	6 (23)	3 (7)	3 (11)	4 (10)	2 (8)	3 (7)	1 (4)	1 (2)	2 (8)	2 (5)	1 (4)	2 (5)	0 (0)	0 (0)	1 (4)	1 (2)	0 (0)	1 (2)
Total 66	21 (81)	23 (57)	8 (30)	6 (23)	6 (23)	11 (27)	3 (11)	6 (15)	8 (30)	13 (32)	1 (4)	3 (7)	1 (4)	2 (5)	2 (8)	4 (10)	1 (4)	4 (10)

Percentage in parenthesis
SP= smear positive TB cases; PRES= presumptive TB cases
Pneum = pneumonia; RT= right lung; LT= left lung; UL= upper lobe; LL= lower lobe
Pleu = pleural effusion; IT lymp = intra thoracic adenopathy
Coll = collapse; B' ect= bronchiectasis

SUMMARY

SUMMARY

1. Out of the 255 suspected pulmonary tuberculosis cases included in the study 66 cases were started on anti tuberculosis treatment which includes both smear positive and presumptive group.
2. Of the 66 cases, 26 cases were smear positive and 40 cases were presumptively started on antituberculosis treatment.
3. No age or gender predilection noted among smear positive or presumptive tuberculosis cases.
4. In both smear positive (76.9%) and presumptive (75%) group majority were from rural population.
5. Cough for more than two weeks was present in all 26(100%) smear positive cases and in 32(80%) of presumptive tuberculosis cases.
6. Fever for more than 2 weeks, breathlessness and loss of weight was higher in smear positive group (76.9%, 69.2%, and 92.3%) compared to presumptive tuberculosis (35%, 50%, and 65%) which was statistically significant.
7. Under nutrition was more common in smear positive (100%) than presumptive pulmonary tuberculosis (75%).
8. Contact positivity observed in children with pulmonary tuberculosis started on antituberculosis treatment was 47%.

Contact positivity was higher in smear positive (65%) compared to presumptive pulmonary tuberculosis (37%).

9. Mantoux positivity observed in children with pulmonary tuberculosis started on antituberculosis treatment was 46%. Mantoux positivity was higher in smear positive (65%) compared to presumptive pulmonary tuberculosis (35%).
10. Pneumonia is the commonest radiological finding (68%) followed by bronchiectasis (9%), collapse (7%), pleural effusion (6%) and intrathoracic adenopathy (1%).
11. Pneumonia was seen in higher proportion of smear positive (81%) than presumptive pulmonary tuberculosis (57%).
12. Induced sputum was smear positive in 9 cases (13.6%) in which gastric lavage was negative.
13. Gastric lavage was smear positive in 4 cases(6.1%) in which induced sputum was negative
14. Overall smear positivity rate was 39 %(26 cases).
15. With smear as reference test, Induced sputum (84.62%) had a higher sensitivity compared to gastric lavage (65.38%), induced sputum (98.43%) had a higher diagnostic accuracy than gastric lavage (96.47%).
16. With smear and presumptive cases as reference test, Induced sputum (33.33%) had a higher sensitivity compared to gastric

lavage (25.76%), induced sputum (82.75%) had a higher diagnostic accuracy than gastric lavage (80.78%).

17. Induced sputum had a higher smear positivity rate (33%) than gastric lavage (26%).

DISCUSSION

DISCUSSION

Worldwide, childhood tuberculosis is an increasing important public-health problem, especially in developing countries. Diagnosis of pulmonary tuberculosis is difficult in infants and young children in whom clinical and radiological signs can be non-specific and variable. **(15)**Hence microbiological confirmation of tuberculosis is desirable for definitive diagnosis and for best use of anti tuberculous medication.

Pulmonary tuberculosis in children is usually paucibacillary (smear negative). Bacteriological confirmation of pulmonary tuberculosis in infants and children remains difficult due to the following reasons like minimal disease or infiltration, minimal cavitations and difficulty in coughing out the sputum.**(2)**

Microbiological confirmation of pulmonary tuberculosis in children has relied on sequential gastric lavage specimens since they do not expectorate but swallow their secretions**. (16)** Studies have shown that gastric aspirate provide a better mycobacterial yield than bronchoalveolar lavage and hence invasive bronchoscopy may be reserved for special situations**. (17, 18)**

Even under ideal circumstances, isolation rates for M tuberculosis from gastric lavage range from 28% to 40% in children with suspected

tuberculosis.**(19, 20, 21, 22)** Microbiological confirmation in young children has been difficult and laborious since two sequential early morning gastric lavage are recommended, and most children need to be hospitalized. Furthermore, this technique is time consuming, needs fasting beforehand, and is distressing to child and health worker. **(19)**

So sputum induction is an alternate technique which has been successfully used in adults,**(23, 24, 13)** previously this technique is not regarded as feasible in young children since they swallow their sputum and do not expectorate but studies showed that sputum induction is feasible in young children.**(12, 6)**

Studies comparing gastric lavage with sputum induction in adults with suspected tuberculosis have reported that the diagnostic yield from sputum induction is higher. **(14, 25, 26, 27)** and studies in children prove that sputum induction is better **(12, 6)** or equivalent **(8)** to gastric aspirate it is not widely practiced in our settings.

Similar to other studies**(6, 2,10)** induced sputum technique had a better sensitivity and diagnostic accuracy than gastric aspirate probably because sputum induction mobilises secretions from lower respiratory tract, improves the sputum transportability, enhance the mucociliary clearance, induce cough and bring out the secretions.

In contrast to gastric lavage which requires overnight fasting and hospitalization sputum induction can be done as an outpatient procedure, and is less invasive and easier to do than gastric lavage. Nevertheless, sputum induction is fairly simple, does not need advanced equipment, and can be taught to health-care workers.

Risk of nosocomial tuberculosis has discouraged some clinicians from using sputum induction in adults **(28, 29)** but risk of nosocomial transmission is lower in children than in adults as bacillary loads is low in children nevertheless adequate precautions should still be taken. Sputum induction can be done without risk even in primary care settings with limited resources care to be taken that sputum collection areas should be well ventilated and protective masks should be worn by health-care workers **(30)**. In our set up sputum induction done in tuberculosis clinic which is separate, well ventilated and personal respiratory protection masks were used.

In contrast to other studies were pulmonary tuberculosis reported commonly in young children **(3, 31)** all ages are equally involved in this study. No gender predilection noted similar to other study **(31)**.

Similar to diagnostic triad for pulmonary tuberculosis in non endemic region observed by Soumya Swaminathan and Banu Rekha which included close contact with an infectious index patient, a positive tuberculin skin test, and presence of suggestive abnormalities on a chest radiograph. In our study triad of loss of weight, a positive tuberculin skin test, and presence of suggestive abnormalities on a chest radiograph were suggestive more in favour of pulmonary tuberculosis.

Contact positivity of children started on antituberculosis treatment was comparable to other study **(32)** and mantoux positivity was higher compared to other studies **(32)**.

In smear positive tuberculosis loss of weight, fever for more than two weeks, under nutrition, contact positivity, mantoux positivity and presence of suggestive abnormalities on a chest radiograph were seen in higher proportion than presumptive tuberculosis which emphasize the need for definitive microbiological confirmation.

Limitations

Due to financial constraint culture of M.tuberculosis was not feasible

- Instead of culture, smear for acid fast bacilli was taken as reference test for statistical analysis.
- Statistical analysis also done using combined smear for acid fast bacilli and presumptively started anti tuberculosis treated cases as reference test.

CONCLUSION

CONCLUSION

Sputum induction is safe and useful for microbiological confirmation of tuberculosis in young children. Sputum induction is more effective than gastric lavage for diagnosis of pulmonary tuberculosis in children.

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ANNEXURE

I.PROFOMA

1.	Patient's Name		
2.	Age		
3.	Sex		
4.	I.P. No.		
5.	Ward No.		
6.	Father's name		
7.	Place		
8.	Address		
9.	Date and time of admission		
10.	Income		
11.	Socioeconomic status		
Clinical history			
12.	History of cough	a) Yes	b) No
	If yes, duration	a) < 2 weeks	b) > 2 weeks
	Type	a) Dry	b) Productive
13.	History of fever	a) Yes	b) No
	If yes, duration		
	Grade	a) Low	b) High
	Chills / Rigors	a) Present	b) Absent
14.	Breathlessness	a) Yes	b) No
	If yes, duration		
15.	Failure to thrive	a) Present	b) Absent
16.	Loss of weight	a) Present	b) Absent
17.	Hemoptysis	a) Present	b) Absent
18.	Significant Past diseases	a) Yes	b) No
	If yes, type of disease		
	Any treatment taken		
19.	History of ATT in the past or at present	a) Present	b) Absent
20.	History of BCG Vaccination	a) Yes	b) No

21.	History of contact with an adult who is diagnosed as Tuberculosis or on ATT in the past 2 years If yes, a) Intrafamilial b)Extrafamilial	a) Yes	b) No

Clinical examination

General examination

22.	Nutritional status If undernourished, WHO centile	a) Normal	b)Undernourished
23.	Pallor	a) Yes	b) No
24.	Lymphadenopathy If present a) Significant or b) Insignificant Site of lymphadenopathy	a) Present	b) Absent
25.	B.C.G. Scar	a) Present	b) Absent
26.	Clubbing	a) Present	b) Absent
27.	External markers of TB	a) Present	b) Absent
	If present, specify		

28. Vital signs

A.	Respiratory rate	
B.	B.P.	
C.	Heart rate	
D.	Temperature	
E.	Pulse	

29. Examination of respiratory system:

Deformity of chest	
Tracheal position	
Apical impulse	
Vocal fremitus	
Type of respiration	
Air entry	
Added sounds	
Vocal resonance	

30. Examination of other system:			
CVS			
Abdomen			
CNS			
31. Chest X Ray findings:			
32	**Mantoux test**	a) Positive	b) Negative

33. Gastric lavage	**a)Positive**	**b)Negative**
1		
2		
34.Induced sputum	**a)Positive**	**b)Negative**
1		
2		

II. ABBREVIATIONS

AFB- acid fast bacilli

ATT- anti tuberculosis treatment

BCG- bacille calmette-Guerin

B'ect- bronchiectasis

BP- blood pressure

Cavity- cavitatory lesions

CI- confidence interval

CNS- central nervous system

Coll – collapse lung

Cont+ - contact positive

CVS- cardiovascular system

F- Female

GL- Gastric lavage

GL1- gastric lavage first specimen

GL2- gastric lavage second specimen

HIV- human immune deficiency virus

IAP- Indian academy of pediatrics

IS - induced sputum

IS 1- induced sputum first specimen

IS 2- induced sputum second specimen

IT lymp- intra thoracic lymphadenopathy

LL- lower lobe of lung

LT- left lung

M- Male

M.tuberculosis- mycobacterium tuberculosis

Mx+ - mantoux positive

Pleu – pleural effusion

Pneum – pneumonia

PPD- purified protein derivative

PRES- presumptive tuberculosis

RNTCP- revised national tuberculosis control programme

RT- right lung

Spo2- oxygen saturation

SP- Smear positive tuberculosis

TB- tuberculosis

TU- tuberculin unit

Un- undernourished

UL- upper lobe of lung

III. CONSENT FORM

ROLE OF INDUCED SPUTUM IN THE DIAGNOSTIC WORK UP OF PULMONARY TUBERCULOSIS IN CHILDREN.

Investigator Name : Dr.C.Vijai Shankar
Guides : Dr.D.Vijayasekaran MD. DCH.
Dr.M.Raghunadan MD. DCH.
Dr.K.Nedunchelian MD. DCH

(To be read to caretakers in the presence of a witness)

Your child is suspected to have tuberculosis infection of the lungs. For diagnosing it demonstrating the organisms in the sputum is essential. There are three methods available for sputum collection, they are

a. Gastric lavage
b. Induced sputum
c. Bronchoalveolar lavage

At present in our hospital sputum collection done by gastric lavage technique. For this method child needs overnight fasting, inserting the nasogastric tube is not well tolerated by children and diagnostic value is less.

Recent studies have shown that sputum induction is relatively easy, well tolerated and gives higher bacteriological yield.

So in this study children suspected of having tuberculosis of the lungs will be subjected for gastric lavage and induced sputum on two consecutive days.

This study is conducted to assess whether induced sputum technique have a better mycobacterial yield compared to gastric lavage technique.

How is the study being done?

The doctor will ask you questions and examine the child to make sure that it is safe for him/her to enter the trial.

If you child is suspected to have tuberculosis of the lungs he/she will be subjected for gastric lavage technique and induced sputums as explained below.

After over night fasting the gastric contents will be aspirated through the nasogastric tube before the child gets up from the bed. This done for two consecutive days.

On the same days sputum induction done using 3% hypertonic saline nebulisation for 10-15 min and sputum will be obtained after cough or by suctioning through the nasopharynx with a sterile mucous extractor.

The specimen obtained by the two methods will be sent for demonstrating the mycobacterium tuberculosis organisms.

Can I refuse to join the study?

You may refuse to participate or withdrawn from this study at any time. In both cases you child will be treated in the usual manner in this hospital.

Is there a benefit or harm to be in this study?

During gastric lavage technique insertion of nasogastric tube may cause some pain but it is transient.

Sputum induction may cause cough vomiting and minimal epistaxis in some children.

Confidentiality

The data collected from the study will be used for the purpose of the study only. The results of the study are to be published. Personal information of the children participating in the study will be kept confidential and there will not be any disclosure about your child's information without your permission.

Subject Rights

I understand that if I with further information regarding my child's rights as a research subject. I may contact the hospital above the study is taking place.

CONSENT

I have been fully informed about the study and the benefits to my child and the possible harm that can happen. I understand that the Doctor will ask question and examine my child to make sure that it is safe for him/her to enter the study.

Method of Gastric lavage technique and induced sputum technique is fully explained to me by the doctor. I will allow my child for this study.

This authorization is valid only for this study. “I have understood and received a copy of the consent form”. I agree for my child’s participation in this research study.

Signature / Thumb Print of Parent / Guardian:

Signature of Investigator :

Witness Signature :

Date :

Principal Investigator :

Address :

Ph :

நுரையீரல் காச நோய் கண்டுபிடிப்பதற்கு. தூண்டி சளி எடுத்தலின் பங்களிப்பு பற்றிய ஆய்வு.

ஆய்வாளர்கள்

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தகவல் தாள்

காச நோய் என்பது குழந்தைகளுக்கு ஒரு உயிர் கொள்ளி நோய் ஆகும். காசநோய் நுரையீரலை தாக்கி இருப்பதை கண்டுபிடிக்க சளி பரிசோதனை அவசியமாகும்.

சளி எடுத்து காச நோய் கிருமி கண்டறிய மூன்று வழி முறைகள் உள்ளன அவை

(i) மூக்கின் வழியே குழாய் விட்டு வயிற்று நீரில் உள்ள சளி எடுத்தல் (Gastric Lavage)

(ii) புகை மருந்தின் மூலம் (3% Hypertonic saline nebulisation) தூண்டிச் சளி எடுத்தல் (Induced Sputum)

(iii) மூச்சு குழாயில் கருவி மூலம் சளி எடுத்தல் (Bronchoalveolar Lavage)

நமது மருத்துவமனையில் தற்போது மூக்கின் வழியே குழாய் விட்டு தொடர்ந்து இரண்டு நாட்கள் சளி எடுக்கும் முறை பயன்படுத்தப்பட்டு வருகிறது. இந்த முறையில் குழந்தைகள் ஓர் இரவு முழுவதும் உணவு உட்கொள்ளாமல் இருக்க வேண்டும். குழந்தைகளுக்கு மூக்கின் வழியே குழாய்

விடுதல் சிரமமானது ஆகும் மற்றும் இதன் மூலம் காசநோய் கிருமி கண்டறியும் எண்ணிக்கையும் மிகவும் குறைவாக உள்ளது.

சில ஆராய்ச்சிகள் மூலம் புகை மருந்து மூலம் தூண்டி சளி எடுக்கும் முறை மூக்கின் வழியே குழாய் விட்டு சளி எடுத்தல் முறையை விட எளிமையாக கருதப்படுகிறது. இதன் மூலம் காச நோய் கிருமி கண்டறியும் எண்ணிக்கையும அதிகமாக உள்ளது.

எனவே இந்த ஆய்வின் மூலம் நுரையீரல் காசநோய் இருக்கும் என சந்தேகிக்கப்படும் குழந்தைகளுக்கு இரண்டு முறையும் கையாளப்படும்.

இந்த ஆய்வின் மூலம் இந்த இரண்டு முறைகளில் எது சிறந்து மற்றும் எளிமையான முறை என கண்டறியப்படும்.

ஆய்வின் நோக்கம்

புகை மருந்து மூலம் தூண்டி சளி எடுக்கும் முறையை காசநோய் கிருமி கண்டறியும் எண்ணிக்கையை மூக்கின் வழியே குழாய் விட்டு சளி எடுக்கும் முறையுடன் ஒப்பிடுதல்.

ஆராய்ச்சி நடவடிக்கைகள்:

ஆராய்ச்சிக்கு உட்படுத்தப்பட்ட குழந்தைகளுக்கு மூக்கின் வழியே குழாய் விட்டு சளி எடுக்க கீழ் வரும் முறை பயன்படுத்தப்படும்.

அக்குழந்தைக்கு ஓர் இரவு முழுவதும் உணவு உட்கொள்ளாமல் இருக்க அறிவுறுத்தப்படும். இதுவே மூக்கின் வழியே குழாய் விடப்படும் காலை படுக்கைவிட்டு எழுவதற்கு முன் குழாய் மூலம் வயிற்கு நீர் எடுத்து பரிசோதனை கூடத்திற்கு அனுப்படுப்படும். தொடர்ந்து இரண்டு நாட்களுக்கு இந்த முறை கடைப்படிக்கப்படும்.

அதே இரண்டு நாட்களிலும் புகை மருந்தின் (3% Hypertonic saline) மூலம் தூண்டி சளி எடுக்கும் முறை (RNTCP) அறையில் கையாளப்படும். இந்த முறையில் சுமார் 10 முதல் 15 நிமிடங்களுக்கு குழந்தைகளை புகை மருந்தை சுவாசிக்க அறிவுறுத்தப்படுவார்கள். பின்பு இதன் மூலம் சளியை இருமச் செய்து அல்லது சளி உறிஞ்சும் கருவி மூலம் எடுக்கப்படும்.

இந்த இரண்டு முறையில் எடுக்கப்படும் சளி பரிசோதனைக்கு அனுப்பப்படும்.

அபாயம் மற்றும் நன்மைகள்

பரிசோதனைக்காக மூக்கு வழியாக சளி எடுக்கும் இடத்தில் சிறிது வலி ஏற்படலாம். இவை தற்காலிகமானது. புகை மருந்து மூலம் தூண்டி சளி எடுக்கும் முறையில் குழந்தைகளுக்கு இருமல், வாந்தி மற்றும் சில சமயங்களில் சிறிது அளவு மூக்கின் வழியே இரத்தம் வர வாய்ப்புள்ளது.

தகவல் அளிக்கப்பட்ட ஒப்புதல் படிவம்

எனது குழந்தைக்கு நுரையீரல் காசநோய் இருக்கலாம் என்று மருத்துவரால் தெரிவிக்கப்பட்டது. சளியில் கிருமி உள்ளதை உறுதி செய்ய மூன்று முறைகள் உள்ளன என்பதை மருத்துவர் தெரிவித்தார். அவை மூக்கின் வழியே குழாய் விட்டு வயிற்று நீரை எடுத்தல், புகை மருந்தின் மூலம் தூண்டிச் சளி எடுத்தல் மற்றும் மூச்சு குழாயில் கருவி மூலம் சளி எடுத்தல்.

மூக்கின் வழியே குழாய் விட்டு வயிற்று நீரில் உள்ள சளி எடுக்கும் முறை மற்றும் புகை மருந்து மூலம் தூண்டிச் சளி எடுக்கும் முறை பற்றி எனக்கு மருத்துவரால் அறிவிக்கப்பட்டது.

இந்த ஆய்வு பற்றி எனக்கு விளக்கமாக எனது தாய்மொழியில் (தமிழ்) சொல்லப்பட்டது. இந்த ஆய்வில் பங்கெடுத்து கொள்வதால் எனது குழந்தைக்கு ஏற்படக்கூடிய அபாயங்கள் மற்றும் நண்மைகள் பற்றி எனக்கு விளக்கப்பட்டது. இந்த ஆய்வில் எனது குழந்தையை பங்கெடுத்துக் கொள்ள முழுமனதுடன் சம்மதிக்கிறேன். கேள்விகள் கேட்பதற்கு எனக்கு வாய்ப்பு அளிக்கப்பட்டது.

இந்த ஆய்விலிருந்து கிடைக்கும் முடிவுகளை பயன்படுத்துபவரை கட்டுப்படுத்தாமலிருக்க நான் சம்மதிக்கிறேன்.

குழந்தையின் பெயர் :

குழந்தையின் பெற்றோர் / கண்காணிப்பாளர் பெயர் :

குழந்தையின் பெற்றோர் / கண்காணிப்பாளர் கையொப்பம் :

தேதி :

சாட்சியின் பெயர் :

சாட்சியின் கையொப்பம் :

தேதி :

ஆய்வாளர் / ஆய்வு மருத்துவர் பெயர் :

ஆய்வாளர் / ஆய்வு மருத்துவர் கையொப்பம் :

தேதி :